

the phenomena with which the invention is concerned is that which may occur when a stent having a lattice structure is placed in a vessel having a small radius of curvature. When such a stent is placed in a curved vessel, portions of its lattice structure may project into the internal lumen of the stent in a manner that compromises the luminal cross-sectional area of the stent. (application 2:14-19). The projection of a portion of the stent into the lumen may be most pronounced on the inside, tighter radius of the vessel curve. Among the objectives of one aspect of applicant's invention is to avoid such obstruction of the stent lumen. This is desirable in blood vessels, for example, in that by avoiding the projection of portions of the lattice into the lumen, uncontrollable vortices in blood flowing in the vessel may be avoided. Vortices and turbulent flow can lead to vessel occlusion.

In applicant's stent, the lattice includes a number of strut-like elements referred to as "wall segments"(18) which are said to "branch off" at intersections, some (22) of which are interrupted but others (20) are not. As acknowledged at page 4 in the application, the prior art discloses stents having interrupted portions adapted to enhance flexibility (3:37-4:14). However, when the stent is curved, as when placed in a narrowly curved vessel zone, the edges of the disconnected (interrupted) portions of the stent may project into the internal lumen of the stent, particularly at the inside of the curve. In one aspect of applicant's invention, that undesirable result is avoided by forming the stent so that the wall segments, particularly those that meet at an interrupted intersection, incline radially outwardly at an angle to the longitudinal direction of the stent. This is illustrated in FIGS. 3 and 5 of the application and, more particularly, in enlarged FIG. 7 which shows applicant's stent placed in a sharply curved blood vessel. FIG. 7 illustrates the strut-like wall segments and the manner in which the ends of the wall segments are "expanded [i.e., curved or bent] in the radial direction." When placed in a curved blood vessel, the radially outward orientation of the ends of the wall segment cannot project into the lumen defined through the stent.

FIG. 6 of the application illustrates a mold in which the configuration of a stent made in accordance with this aspect of applicant's invention can be preformed to assure that the wall segments, particularly those at the interrupted intersections, inclined radially outwardly.

THE CITED PRIOR ART

U.S. Patent 5,514,154 (Lau)

The Lau patent is directed to a stent having a plurality of radially expandable cylindrical elements, each of which being defined in a somewhat serpentine pattern. Adjacent hoop-like cylindrical elements are connected to each other by interconnecting elements 13. Some of the peaks defined by the serpentine configuration are not associated with interconnecting elements. The serpentine pattern 30 is said to be made up of a plurality of U-shaped members 31, W-shaped members 32 and Y-shaped members 33. The stent is formed from a cylindrical tube by chemical etching. As near as can be determined from Lau, all of the components of the stent, including the U-shaped, W-shaped and Y-shaped members lie in the cylindrical wall of the stent. Lau explains, however, that "...during radial expansion U-shaped members 31 will tip outwardly thereby forming outwardly projecting edges...[that] provide for a roughened outer wall surface of stent 10 and assist in implanting the stent in the vascular wall by embedding into the vascular wall." (Lau 6:19-24). Lau also states that "...any of the U-shaped members 31, W-shaped members 32 and Y-shaped members 33 can tip radially outward to form a projecting edge 34 [, it] is *most likely* and preferred that U-shaped members 31 tip outwardly ...". (6:28-32). (emphasis supplied).

European Patent Application 792627A2 (Fogarty)

Fogarty discloses a stent having a wall thickness between about 0.1 millimeter and 0.5 millimeter.

CLAIM REJECTIONS - 35 U.S.C. §112

The requirement that the claims "particularly point out and distinctly claim" the invention is met when a person experienced in the field of the invention would understand the scope of the subject matter that is patented when the claim is read in conjunction with the rest of the specification. "If the claims when read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, §112 demands no more." Miles Laboratories, Inc. v. Shandon, 997 F.2d 870, 875, 27 USPQ2d 1123, 1126 (Fed. Cir. 1993); see also Union Pacific Resources Co. v. Chesapeake Energy Corp., 236 F.3d 684, 692, 57 USPQ2d 1293, 1297 (Fed. Cir. 2001); North American Vaccine, Inc. v. American Cyanamid Co., F.3d 1571, 1579, 28 USPQ2d 1333, 1339 (Fed. Cir. 1993); Hybritech, Inc. v. Monoclonal Antibodies, 802 F.2d 1367, 1385, 231 USPQ 81, 94-95 (Fed. Cir. 1986).

As to claim 6, the reference to "cents" in claim 6 is an obvious typographical error. Where "wall cents" was not part of an amendment, the form of the original claim 6 governs. Original claim 6 plainly uses the term "wall segments". As to the questions concerning how the width is measured, that is explained in the written description and need not be set out in the claim. Moreover, it is the width of the wall segment, not the width of the intersection that is claimed. The action does not explain why the scope of the claim, read in conjunction with the rest of the specification would not be understood by one of skill in the art.

As to claim 27, that has been amended to include the positive recitation of the stent delivery system in the body of the claim. That amendment, however, is considered to be no more than cosmetic because the element of the stent delivery system was present in the claim before the amendment. Here, again, there is no basis in the action to support the notion that one of ordinary skill would not have understood the scope of the claim. The same is true with respect to claim 29 and the amendment by which "application system" has been changed to --delivery system--. While the

choice of language may not have been consistent, the inconsistency was not such that one of ordinary skill would not have understood the scope of the claim. The same applies with respect to claim 30 which has not been amended.

CLAIM REJECTIONS - 35 U.S.C. §102

Anticipation under 35 U.S.C. §102 requires that each and every limitation of the claim is disclosed in a single prior art reference, either expressly or inherently. The anticipating reference must disclose the elements in the arrangement called for by the claim. If any limitation of the claim is missing, the reference does not anticipate.

Reconsideration is requested of the rejection of claims 1, 3, 8-10 and 27-29 as anticipated by Lau '594. Lau does not disclose a stent having "...wall segments [that] are expanded in the radial direction...such that, upon curvature of the stent along the longitudinal direction, a reduction of the inner lumen due to the wall segments at the interrupted intersections is prevented." Although Lau discloses a longitudinally flexible stent in which some portions of the undulating pattern of the stent will "tip outwardly" to project outwardly from the outer surface of the stent to secure the stent to the vessel tissue, that is not the same as avoiding obstruction of the lumen of the stent when the stent is bent. There is nothing in Lau that recognizes the problem with which this aspect of applicant's invention is concerned and there is nothing in Lau to describe an intentional structure designed to reduce the incidence of that problem. It does not necessarily follow that the "outward tipping", which is only said to serve as a means for embedding the stent in the vascular wall to secure the stent in place, would not prevent part of Lau's cylindrical member 12 from projecting into the lumen of the stent when the Lau stent is placed in a curved vessel. Moreover, in Lau, the U-shaped members apparently are caused to tip outwardly only as a consequence of the radial balloon expansion of the stent, not by the stent being formed to have applicant's claimed "radially expanded wall segments". In Lau, any outward tipping of any portion of the stent is a consequence, perhaps originally unintended, of the radial expansion of the

stent, not of any design characteristic, such as the stent having applicant's claimed radially expanded (flared) wall segments. Certainly, there is nothing in Lau to suggest that when the Lau stent is curved, as when being placed in a curved vessel, its stent components will not project into the stent lumen. Indeed, Lau appears to be less than certain as to the manner in which the device operates. Lau, at most, surmises that the U-shaped members 31 tip outwardly when the stent is expanded. "...it is *most likely* and preferred that U-shaped members 31 tip outwardly since they do not join with any connecting member 13 to prevent them from expanding outwardly." (6:30-33). emphasis supplied).

CLAIM REJECTIONS - 35 U.S.C. §103

Reconsideration is requested of the rejection of claims 4, 5, 11 and 30 as defining subject matter that would have been obvious in view of Lau. These claims include the same limitations discussed above in connection with claim 1. Lau fails to suggest the claim limitation of the wall segments being expanded in a radial direction so that upon curvature of a stent a reduction of the inner lumen is prevented. There is nothing in Lau to disclose or suggest a stent having radially expanded wall segments that do not interfere with the lumen of the stent when the stent is curved longitudinally. In the absence of evidence to support the rejection, the rejection is improper and should be withdrawn.

As to the limitations that the action acknowledges are not disclosed in Lau (two-thirds of all intersections being interrupted, aperture widths of maximally 9 millimeters when the stent is expanded, and alloy moieties merely characterizing those claimed features as "...a matter of design choice" is no substitute for evidence.

In cases where a single prior art reference is alleged to render the claimed invention obvious, there must be a sufficient showing of a suggestion or motivation for any modification of the teachings of that reference necessary to reach the claimed invention in order to support the obviousness conclusion. *Sibia Neuroscis., Inc. v.*

Cadus Pharm. Corp., 225 F.3d 1349, 1356, 55 USPQ2d 1927, 1931(Fed. Cir. 2000); *B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 72 F.3d 1577, 1582, 37 USPQ2d 1314, 1318(Fed. Cir. 1996). This suggestion or motivation may be derived from the prior art reference itself, from the knowledge of one of ordinary skill in the art, or from the nature of the problem to be solved. *Sibia*, 225 F.3d at 1356, 55 USPQ2d at 1931. *McGinley v. Franklin Sports, Inc.* 262 F.3d 1339, 60 USPQ2d 1001 (Fed. Cir. 2001). The action does not explain any reason for one to have been motivated to modify Lau so that the portions of the stent in Lau would not project into the lumen defined by the stent when the stent is curved.

Claim 7 includes the same limitations of claim 1. Fogarty does not disclose those features of applicant's invention, discussed above, that are missing from Lau.

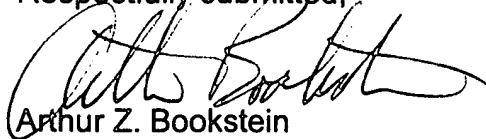
Reconsideration of the rejection of claim 7 is requested.

THE RESTRICTION REQUIREMENT

Reconsideration is requested of the restriction requirement between the process and the product claims. The process defined in claim 12 includes the step of expanding the wall segments at least at the interrupted intersections so that upon curvature of the stent the inner lumen of the stent will not be reduced by the wall segments. There is no support in the action for the conclusion that that process could be used to make anything but the stent defined in claim 1. Moreover, there is nothing to support the conclusion expressed in the action that the stent defined in claim 1 could be made by a process that does not include all of the steps of claim 12. Here, the claimed stent and the claimed process for making the stent are intimately related such that searching and consideration of one necessarily requires searching and consideration of the other. The mere statement that the stent could be made by the process of molding, welding or chemical etching is beside the point. Claim 12 would not exclude making the stent by molding, welding or etching. Where there has been no showing that the inventions claimed are distinct or that they have acquired a meaningful separate status in the art,

restriction is improper, its withdrawal is requested and examination on the merits of patentability of all of the claims is requested.

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims

Claim 27 has been amended as follows:

27. (Amended) A combination of an expandable stent and a stent delivery system wherein comprising:
the stent comprises an elastic tubular lattice structure having a first end zone, a second end zone, a longitudinal direction and a radial direction, the lattice structure defining an outer diameter and an inner lumen and being formed by wall segments, which wall segments branch off at intersections, and the lattice structure being interrupted at least some of the intersections, so as to increase the flexibility of the stent, wherein the wall segments are expanded in the radial direction at least at the interrupted intersections such that, upon curvature of the stent along the longitudinal direction, a reduction of the inner lumen due to the wall segments at the interrupted intersections is prevented; and
the stent delivery device for delivering the stent.

Claim 29 has been amended as follows:

29. (Amended) A combination in accordance with claim 27, wherein the application delivery system is a system in accordance with the Seldinger technique for catheterization of bodily vessels.